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Interview summary

Interviewee: Maddalena Illario, Federico II University, Italy
mHealth Practice: **PROEMPOWER**
Interviewers: Vincenzo De Luca
Date of interview: 2020-12-10

Topics

ProEmpower has a successful approach to the following topics:

- Initiation > **Needs assessment**
- Execution > **Solution testing and validation**

Summary

- PROEMPOWER is a Pre Commercial Procurement co-financed by Horizon 2020 programme, aimed to procure a disease self-management mHealth solution to help meet the imminent threat of type 2 diabetes mellitus;
- 4 Procurers: Ministry of Health of Turkey; Servicio Murciano de Salud, Murcia; Servico Partilhados do Ministerio de Saude; Federico II University Hospital / Società Regionale per la Sanità SpA, Campania Region;
- Procurement Budget: € 3.000.000;
- Co-designed method to define the functional and non-functional requirements of the mHealth solutions;
- Development and testing of pilot systems in 4 pilot sites.
- Early identification of diabetes
- Shared Care Plan
- Personalized treatment and remote monitoring
- Coaching and promoting healthier lifestyles
- Co-operative diabetes support (peer-to-peer support)
- Training to diabetic patients
- No technology-driven, but clearly meet specific needs of patients and health professionals in effective healthcare service delivery.

Scope of mHealth Practice

Background info about the good practice

ProEmpower is an European funded project under Horizon 2020 programme, with the aim of purchasing R&D services, through a Pre Commercial Procurement procedure, in order to develop innovative IT solutions for early diagnosis and management of diabetes, facilitating the lives of people with type 2 diabetes, supporting them in their daily lifestyle choices and giving healthcare professionals access to the clinical data needed for the management of the disease and its

complications. The project involves four public procurers across Europe – Turkey, Portugal, Campania and Murcia.

Summary of main interview ideas

The interview covers two main phases of the procedure:

- The method used to define the functional and non-functional requirements of the solutions for patient empowerment and self-management of diabetes;
- The results of the Research and Development activities and the pilot implementation in the 4 pilot sites.

Scope and timeline of the mHealth good practice implementation

- How long did it take for the mHealth practice to be implemented?

ProEmpower is a competitive 40 months R&D process comprising two preparatory steps and three phases:

- Open Market Consultations: dedicated workshops organised by the procurers in their regions to consult with vendors, inform the technical specifications and set realistic, yet innovative procurement objectives;
- Call for Tenders: an international tender launched on the website of the Supplement to the Official Journal of the EU;
- PCP Phase I: Concept design, solution architecture and technical specifications;
- PCP Phase II: Development of prototype systems;
- PCP Phase III: Development and testing of pilot systems.

- What are the key steps that were undertaken?

The **co-design process** of the solution encompasses requirements analysis, iterative development of uses cases and service process models as well as **the development and conduction of training activities supporting the necessary change management in each country or region**.

The collected information was used to inform the elaboration of **functional, non-functional, legal and regulatory requirements**. A set of **use cases and service process models** has been developed in ProEmpower. Each use case is described in full detail with one corresponding process model.

Use Case development includes the following activities:

- Identify all the different **users** of the system;
- Create a user profile for **each category** of user;
- Identify all the significant **goals** the users have that the system will support;
- Create a **use case** for each goal;
- Maintain the same level of abstraction throughout the use case.

An international call for tenders, articulated in phases, selected vendors to implement R&D services for the development of IT solutions addressing Diabetes Type 2.

During phase I, the contractors worked on improving the solution design of the offers made during the call for tenders. The vendors developed in detail the solution design and determined the innovative solutions to be implemented during the subsequent phases. They provided details regarding the technical, financial and commercial feasibility of the proposed concepts and

explained the approach to be used to meet the procurement requirements.

During phase II, the suppliers produced two versions of prototypes of their systems. The prototype demonstration was conducted as face-to-face meetings be-tween the supplier and each procurer, at the procurers' premises. The procurers invited healthcare professionals and patient representatives in order to receive feedback to be used in the evaluation process. The feedback was in form of answers to a questionnaire (one for patients and one for the healthcare professionals). The results were considered when evaluating the suppliers based on the award criteria (e.g. value of benefits for patients).

During phase III two solutions have been tested by end-users (patients and health professionals) enrolled by healthcare organisations of the four procurers. The aim of **the pilot study** was to test the **feasibility, effectiveness and usability** of incorporating the two solutions into the **current care pathway** for patients with type 2 diabetes. Study objectives were to evaluate **direct and indirect outcomes** linked to the use of the novel solutions, including:

a) **behavioural changes**:
   i. smoking habits;
   ii. physical activity;
   iii. steps;
   iv. meals;
   v. medication adherence;
b) **clinical and quality of life (QoL) outcomes**:
   i. HbA1c;
   ii. weight;
   iii. blood pressure (BP);
   iv. blood lipids;
   v. cholesterol;
   vi. quality of life;
c) **satisfaction, self-management and usability**.

- What are the strengths and weaknesses of the implementation process?

In terms of requirements elicitation, **users** (Patients and Health Professionals) are actively involved in identifying needs and providing **opinion on** possible functions (**functional requirements**) which are given to them through a questionnaire. It contains also open questions to capture users' creative wishes in term of requirements expected from ProEmpower. Users are understood as diabetic patients, healthcare professionals treating them, and **informal carers** who help patients with their daily diabetes management.

- Is there a workplan that can be included as a reference? Is there further documentation about the approach?

The approach has been presented in the International Conference **ICT4AWE 2019** and published on a Scientific Journal:

- De Luca V. et al. (2020) Developing a Digital Environment for the Management of Chronic Conditions: The ProEmpower Experience of a Horizon 2020 PCP for Type 2 Diabetes. In: Ziefle M., Maciaszek L. (eds) Information and Communication Technologies for Ageing Well and e-Health. ICT4AWE 2019. Communications in Computer and Information Science, vol 1219. Springer, Cham. https://doi.org/10.1007/978-3-030-52677-1_1

- De Luca V, et al. (2019) European Specifications for Value-based Pre-Commercial Procurement of Innovative ICT for Empowerment and Self-management of Diabetes Mellitus

Patients. Proceedings of the 5th International Conference on Information and Communication Technologies for Ageing Well and e-Health (ICT4AWE 2019), pages 19-27. doi: 10.5220/0007638700190027

- What are the strengths and weaknesses of the solution?

The aim of the project has been the development of ICT solutions to support healthcare professionals and patients, in the early identification of diabetes, the personalization of treatment and remote monitoring, according to the stage of the disease, the blood pressure and blood glucose control and weight management, promoting healthier lifestyles, training, peer-to-peer support.
The strengths are in the integration of multiple solutions in "one stop shop" for users. Interoperability features might be still strengthened, especially towards GPs.

Stakeholder involvement

- What stakeholders needed to be involved for the good practice to work?

Patients, informal caregivers and Health Professionals (General Practitioners, Diabetologists, Nurses)

- What are the stakeholders' roles and activities/effort?

Proempower is developed according to the **international guidelines for diabetes management**. The solution allows patients to **self-monitor**, periodically updating clinical data and monitoring data related to physical activity and nutrition. Healthcare professionals can remotely monitor the patient's progress towards treatment goals by accessing a set of data, including life-styles, and tailor/adjust interventions.

- How was involvement and buy-in of the stakeholders secured?

During the co-design phase, each procurer created a **working group** that included physicians, nurses, IT managers and patients, who represented the unmet needs of professionals and patients for diabetes management. This allowed identifying **a set of use cases and process models** that guided vendors in developing the solutions.

Barriers

Administrative implementation was at first a bottleneck, as it was the first PPI and it was difficult to share with decision makers its added value for the organization and the regional health system at large.

Still the economic resources available to the expert teams supporting the implementation should be improved.

Success factors

Early involvement of clinical experts is a key element to ensure that the solution addresses real issues in service provision. It also facilitates patients involvement. Scientific societies can be a powerful accelerator for identification of key-processes and future scale-up.

Lessons learnt

We learned that PCPs are more sustainable to implement if their goals are aligned with organization priorities and activities, in the framework of a strategy for digital transformation of health and care.

Outcomes

- What were the main outcomes of implementing the mHealth solution?

Two solutions have been selected for phase III and tested with patients in real healthcare settings: **DM4ALL and DiaWatch**.

DM4ALL digital platform includes web and mobile interfaces along with intelligent medical devices, able to support all the diverse needs of the T2DM care pathway. Patients, Informal Caregivers, and Healthcare professionals are able to manage, communicate, and monitor the disease progression through the system. Thus, this multi-pronged and integrated approach promotes self-care practices and continuous monitoring. DM4ALL is developed based on the **Shared Care Plan** (SCP), a "document" including information about lifestyles, treatment plan, and disease-related markers. Furthermore, it collects information and feedback from the patients through validated questionnaires aiming at increasing impact and personalization.

DiaWatch is a mHealth and telemedicine solution to provide a more effective and personalised T2DM management. DiaWatch presents a sensing system platform, that operates using a smartphone optionally integrated with other devices such as a wristband, a glucose monitoring sensor, a blood pressure meter and a scale. The DiaWatch's **Virtual Coach** based on an artificial intelligent system to profile the patient and make appropriate recommendations for diabetes treatment, exercises and healthy lifestyles. A patient personal profile and related data-entry functions are embedded in a SCP progressively updated with new data from different sources. The desktop and mobile interface for clinicians allows professionals to monitor compliance to treatment and goals, to communicate with patients (via textual messages, audio and video features) directly from the healthcare facility, and to identify people at risk of developing diabetes or acute conditions. DiaWatch presents a **social community tool** for interaction, communication and peer training. A cloud-based platform ensures data exploitation for risk prediction.

- What is the status? (pilot, tested, fully operational)

The ProEmpower project consortium launched a call for tenders, articulated in 3 phases to select solutions. During Phase I, the technical, economic and organizational feasibility of five alternative solutions has been assessed. Phase II aimed to verify the main characteristics of three prototypes. During phase III **two solutions have been tested by 200 end-users each** (patients and health professionals) enrolled by healthcare organisations of the four procurers.

Continuous learning and outlook

- What would you have done differently? What can still be improved?

I would have strengthened engagement with local network of specialists, and connect with patient association. Still unsolved an adequate engagement of policy makers and decision makers, pivotal to speed the scale-up.

- What are the future plans for exploiting the mHealth solution?

During the COVID-19 pandemic, Federico II University Hospital, in order to safely guarantee urgent health services, has activated **telemedicine procedures** and related administrative and clinical-assistance procedures. These procedures required the use of dedicated IT tools, including

ProEmpower. The activation of these paths was already started on 30 March 2020, following Campania Region emergency directive aimed at protecting the health of citizens with diabetes.

Therefore, for the purpose of procuring one of the ProEmpower solutions, in addition to **evaluations of an economic nature regarding the reimbursement of the service**, it is necessary to **implement a further clinical trial to verify the effectiveness and safety of the ProEmpower solutions**, in order to make them available to public health organisations. **Federico II University and Hospital expressed their interest** in further development of the clinical testing of solutions both to improve patient monitoring and management, and to pursue its research objectives. Federico II University Hospital would like to test the solutions in more detail, **engaging in dialogue with suppliers through a PPI project** aimed at procuring a more mature version of the solution.

Watch the **video** about this initiative here (access to playlist)